

**REMARKS**

Favorable reconsideration of the subject application is respectfully requested in view of the above amendments and the following remarks. Following the amendments, claims 2, 3, 10-13, 15-17, 31, 33 and 37-43 are pending and under examination, with claims 2, 3, 31, 33, 39, 41 and 43 being in independent format.

Applicants wish to thank the Examiner for the telephone interview with their representative, Janet Sleath, on October 6, 2010.

Claim 4 and previously withdrawn claims 34-36 have been cancelled from the application, and claims 37-43 have been added.

Independent claims 2, 3, 31 and 33 have been amended to recite methods employing, and therapeutic food kits and foodstuffs comprising, a heat moisture-treated waxy maize starch that is prepared by treating waxy maize starch under conditions of 15-30% moisture at a temperature of 95-130°C for a period of 16-24 hours. Support for these amendments can be found, for example, in paragraph 0076 of the published application. Claim 15 has been amended to correct a minor error in the claim language and to recite that the starch does not cause a peak in blood glucose concentration of greater than 9.0 mmol l<sup>-1</sup>. Support for this amendment can be found, for example, in paragraph 0048 of the published application. Claim 16 has been amended to correct a minor typographical error.

Newly added claim 37 depends from independent claim 3 and is drawn to methods wherein the heat moisture-treated starch is prepared by treating waxy maize starch under conditions of 20% moisture at a temperature of 105°C for a period of 16 hours. Support for this claim can be found, for example, in paragraph 0076 of the published application. Newly added claim 38 is also dependent on claim 3 and is drawn to methods wherein the heat moisture-treated starch shows increased susceptibility to enzymatic degradation compared to untreated waxy maize starch. Support for claim 38 can be found, for example, in paragraphs 0077-0082 of the published application.

Newly added independent claims 39 and 41 are drawn to methods of treating hypoglycaemia and preventing or decreasing hypoglycaemic episodes, respectively, by administering a therapeutic food composition comprising a waxy maize starch which is a heat

moisture-treated starch, wherein the food composition comprises per unit dose sufficient starch to maintain blood glucose concentration of greater than 3.0 mmol l<sup>-1</sup> at 300 min post administration and wherein the starch does not cause a peak in blood glucose concentration of greater than 9.0 mmol l<sup>-1</sup>. Similarly, newly added claim 43 is drawn to a therapeutic food kit including a therapeutic food composition comprising per unit dose sufficient starch to maintain blood glucose concentration of greater than 3.0 mmol l<sup>-1</sup> at 300 min post administration and wherein the starch does not cause a peak in blood glucose concentration of greater than 9.0 mmol l<sup>-1</sup>. Support for claims 39, 41 and 43 can be found, for example, in paragraph 0048 of the published application, and throughout the specification as originally filed. Claims 40 and 42 are dependent on claims 39 and 41, respectively, and mirror the subject matter of claims 10-12.

It is urged that support for all the above amendments may be found throughout the specification as originally filed, and that none of the amendments constitute new matter. Applicants specifically reserve the right to pursue claims to any subject matter that may have been cancelled from the claims by the above amendments in one or more related patent applications.

#### Claim rejections under 35 USC §103(a)

Claims 2-4, 10, 11, 13-16, 31 and 33 stand rejected under 35 USC §103(a) as being unpatentable over US Patent 5,605,893 to Kaufman (“Kaufman”) either by itself or in view of Anderson et al., Starch, vol. 54, 2002, pp. 401-409 (“Anderson et al.”). This rejection is respectfully traversed.

Applicants note that claim 4 has been cancelled, thereby rendering the rejection of this claim moot.

Following the above amendments, independent claims 2 and 3 are drawn to methods of treating hypoglycaemia and preventing or decreasing hypoglycaemic episodes by administering a food composition comprising a heat moisture-treated waxy maize starch that is prepared by treating waxy maize starch under conditions of 15-30% moisture at a temperature of 95-130°C for a period of 16-24 hours. Similarly, independent claims 31 and 33 are drawn to a therapeutic food kit and a sports nutrition foodstuff, respectively, that each contain a heat moisture-treated waxy maize starch prepared by treating waxy maize starch under conditions of 15-30% moisture at a temperature of 95-130°C for a period of 16-24 hours. As noted in paragraphs 0065 and 0066

of the instant published application, waxy starches contain a significantly higher percentage of amylopectin and a lower percentage of amylose than normal, or non-waxy, starches, with waxy starches containing less than about 20% amylose and normal starches containing 20-40% amylose. Starches containing more than about 40% amylose are referred to as high amylose starches. This difference in amylose and amylopectin content results in differences in the degree of crystallinity, with waxy starches having a greater proportion of crystallinity than non-waxy starches, and corresponding differences in digestibility *in vivo*.

As discussed in the Amendment and Reply filed on May 10, 2010, applicants have determined that heat moisture treatment of waxy maize starch under the specific conditions described in the present specification and recited in independent claims 2, 3, 31 and 33 results in a treated starch that has a beneficial and unexpected glucose release profile when administered to patients. For example, as described in Example 6 of the specification (paragraphs 0127-0134 of the published application) and shown in Fig. 10, the initial spike in blood glucose levels following administration was found to be significantly less for heat moisture-treated waxy maize starch than for native waxy starch. As a result, it was possible to feed patients more of the heat moisture-treated waxy maize starch than the untreated waxy starch, which lead to an extended period within which the blood glucose level was maintained at an acceptable level.

The beneficial and unexpected properties of the inventive heat moisture-treated waxy maize starch are discussed in the declaration of Professor Richard Tester submitted herewith and are further evidenced in the references of Bhattacharya et al., (J. Inherit. Metab. Dis, 30:350-357, 2007; previously submitted), Correia et al. (Am. J. Clin. Nutr., 88:1272-6, 2008; copy submitted herewith as Exhibit A), and Roberts et al. (Nutrition, in press, 2010; copy submitted herewith as Exhibit B).

The Bhattacharya et al. reference was discussed in the Amendment and Reply filed on May 10, 2010. Correia et al. describe a randomized, double-blinded, clinical study in which patients with Type I glycogen storage disease (GSD) were treated with either uncooked cornstarch or with the inventive heat-moisture treated waxy maize starch (referred to in the reference as “experimental starch”). In the abstract (page 1272), Correia et al. state “The experimental starch was superior to standard therapy in preventing hypoglycemia (<60 mg/dL). This therapy may allow patients with GSD to sleep through the night without awakening for therapy while enhancing safety.” Roberts et al. describe studies demonstrating that the inventive

heat-moisture treated waxy maize starch “blunted the initial spike in serum glucose and insulin and increased the breakdown in fat” compared to maltodextrin (abstract, first page).

Kaufman discloses a therapeutic food composition for diminishing fluctuations in blood sugar levels and preventing hypoglycemic episodes in diabetic patients that comprises a slowly absorbed complex carbohydrate, a more rapidly absorbed complex carbohydrate, protein and fat. At col. 3, lines 63-67, Kaufman states that the slowly absorbed carbohydrate is preferably uncooked cornstarch. Kaufman does not teach or suggest a food composition including a heat moisture-treated waxy maize starch as recited in the pending claims. Indeed applicants have been unable to find any reference in Kaufman to waxy starches, either native or heat-moisture treated.

The Anderson et al. reference is mostly concerned with heat moisture-treated waxy and non-waxy rice starches, but includes a comparison of the properties of the heat moisture-treated rice starches with those of other heat moisture-treated starches. Specifically, Anderson et al. describe the preparation of various heat-moisture treated starches, followed by measurement of their *in vitro* digestibility as determined by the amount of maltose released during treatment with porcine alpha-amylase. The teachings of Anderson et al. with respect to heat moisture-treated waxy corn starches are, at best, contradictory. For example, in the abstract (page 401) Anderson et al. state “Heat-moisture treatment of waxy corn, non-waxy corn and wheat starches at the  $T_m$  determined for non-waxy rice starch did not result in significant decreases in digestibility.” However, in the left-hand column on page 406, when discussing the *in vitro* digestibility results shown in Fig. 6, the reference states “Heat-moisture treated waxy corn and non-waxy corn starches all showed reduced digestibility relative to the respective controls”. The actual results shown in Fig. 6 for the waxy and non-waxy corn starches are somewhat difficult to discern.

As discussed in the Declaration of Dr. Richard Tester submitted herewith, *in vitro* studies on the digestibility of starches are of limited value for predicting *in vivo* digestive profiles. However, as evidenced in the enclosed Declaration, a reduction in digestibility as reported by Anderson et al. for rice starches would in fact lead to an undesirable outcome upon administration to patients suffering from, or at risk of, hypoglycemia.

Anderson et al. do not teach or suggest the preparation of heat-moisture treated waxy starches using the specific conditions recited in independent claims 2, 3, 31 and 33. In the telephone interview on October 6, 2010, the Examiner stated that the heat moisture treatment

conditions recited in the present claims are taught in the right hand column on page 401 of Anderson et al. However, applicants note this section of Anderson et al. refers to the teachings of Shi and Trzasko, US Patent 5,593,503 (“Shi et al.”). Shi et al. disclose a process for preparing an amylase-resistant granular starch from a *high amylose* starch having at least 40% by weight of amylose. As discussed above, high amylose starches are very different to waxy starches, which contain less than about 20% amylose. Thus Shi et al. do not teach or suggest the preparation of heat moisture-treated *waxy* starches using the conditions recited in independent claims 2, 3, 31 and 33.

In view of the differences between the presently claimed invention and the teachings of Kaufman and Anderson et al., plus the unexpected and unpredictable beneficial properties of the inventive heat moisture-treated waxy maize starch, it is submitted that neither Kaufman et al. nor Anderson et al., taken either singly or in combination, would have rendered the presently claimed subject matter obvious to one of skill in the art and that the rejection of claims 2, 3, 10, 11, 13-16, 31 and 33 under 35 USC §103(a) should thus be withdrawn.

Claims 2-4, 11-14, 17, 31 and 33 stand rejected under 35 USC §103(a) as being unpatentable over WO 02/34271 to Hansson et al. (“Hansson et al.”) in view of Anderson et al. Claim 4 has been cancelled, thereby rendering the rejection of this claim moot. The rejection of claims 2, 3, 11-14, 17, 31 and 33 is respectfully traversed.

Hansson et al. disclose and claim methods for treating dysglucaemia, such as nighttime hypoglycemia in diabetic patients, by administering a composition comprising a starch in a granulated form. The surface area of the starch available to enzymatic action is minimized by granulating the starch with a substance in order to provide aggregated granules which are encapsulated, at least partially, by the substance. The reference teaches that this encapsulation enables regulation of enzymatic degradation of the starch *in vivo* “in an accurate and repeatable manner” (pg. 7, lines 19-23). At various places in the application, Hansson et al. state that the starch is “preferably native cornstarch” (see, for example, page 8, lines 14-15).

Hansson et al. state that the composition may also comprise heat treated cornstarch, preferably “in the form of baked flakes, which give the product a crispy texture and a pleasant taste”. The flakes are prepared from a mixture of cornstarch, water, sodium chloride and sweetener (see, pg. 10, lines 13-18). It appears that the flakes are added solely to make the composition more palatable and appealing to the patient.

Hansson et al. do not teach or suggest heat-moisture treated starches prepared using the specific conditions recited in independent claims 2, 3, 31 and 33. Furthermore, applicants have been unable to find any reference in Hansson et al. to waxy starches.

The teachings of Anderson et al. are discussed in detail above. Anderson et al. do not overcome the deficiencies of Hansson et al.

It is urged that neither Hansson et al. nor Anderson et al., taken either singly or in combination, would have rendered the presently claimed subject matter obvious to one of skill in the art at the time the invention was made, and that the rejection of claims 2-4, 11-14, 17, 31 and 33 under 35 USC §103(a) can thus be properly withdrawn.

**Concluding Remarks**

A request for a one month extension of time, extending the deadline for responding to the final Office Action to November 22, 2010, is submitted herewith.

Every effort has been made to put the claims in condition for allowance. Early reconsideration and allowance of the amended claims is respectfully requested. Should the Examiner have any questions or concerns regarding the application, she is respectfully requested to telephone the undersigned at (206)382.1191.

Respectfully submitted,

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